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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,731	02/19/2008	Bakulesh Mafatal Khamar	21059/0206949-us0	8375
7278	7590	05/04/2010		
DARBY & DARBY P.C. P.O. BOX 770 Church Street Station New York, NY 10008-0770			EXAMINER SWARTZ, RODNEY P	
			ART UNIT 1645	PAPER NUMBER
			MAIL DATE 05/04/2010	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/583,731

**Applicant(s)**

KHAMAR ET AL.

**Examiner**

Rodney P. Swartz, Ph.D.

**Art Unit**

1645

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 1 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21, 23, 24 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-21 is/are allowed.
- 6) ☒ Claim(s) 23, 24 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicants' Response to Office Action, received 1 February 2010, is acknowledged. Claim 3 has been amended. Claims 22, 25 and 26 have been cancelled.
2. Claims 1-21, 23, 24 and 29 are pending and under consideration.

### Rejections/Objections Moot or Withdrawn

3. The rejection of claims 3 and 4 under 35 U.S.C. 112, second paragraph, as being indefinite for "comprises", is withdrawn in light of the amendment of the claims.
4. The objection of claim 22 under 37 CFR 1.75 as being a substantial duplicate of claim 1 is moot in light of the cancellation of the claim.
5. The objection of claim 25 under 37 CFR 1.75 as being a substantial duplicate of claim 1 is moot in light of the cancellation of the claim.
6. The objection of claim 26 under 37 CFR 1.75 as being a substantial duplicate of claim 1 is moot in light of the cancellation of the claim.

### Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 23 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for utilizing *Mycobacterium w* as an adjuvant with an antigen, does not reasonably provide enablement for composition of *Mycobacterium w* and an unidentified antigen which prevent all diseases in mammals (claim 23) or decrease morbidity and mortality associated with all disease (claim 24). The specification does not enable any

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention – compositions of *Mycobacterium w* and an unidentified antigen which prevent all diseases in mammals (claim 23) or decrease morbidity and mortality associated with all disease (claim 24).

The state of the prior art indicates that the instant inventors are the originators of utilizing *Mycobacterium w* as an immunomodulator (WO02/056898A2, 25July2002). However, the prior art does not teach *Mycobacterium w* as an adjuvant coupled with an antigen. Thus, there is a lack of predictability in the art that *Mycobacterium w* as an adjuvant coupled with any antigen will result in prevention of all diseases in mammals or in decreased morbidity and mortality associated with all diseases.

The amount of direction/guidance/working examples present in the instant specification is insufficient support for the broad scope of the instant claims, i.e., prevention of all diseases or decreased morbidity and mortality associated with all diseases. The only examples provided utilized *Mycobacterium w* coupled with either rabies vaccine or coupled with Hepatitis B vaccine.

Therefore, the quantity of experimentation necessary to determine if compositions of *Mycobacterium w* coupled with any antigen can prevent diseases or decrease morbidity and mortality associated with disease in those situations wherein said antigen has no identity with said disease constitutes merely an invitation to experiment without a reasonable expectation of success.

### **Claim Rejections - 35 USC § 102**

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claim 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Bakulesh et al (WO02/056898A2, 25 July 2002).

Claim 29 is drawn to *Mycobacterium w* and/or a constituent thereof as an adjuvant to an antigen.

Thus, the only component of claim 29 is *Mycobacterium w* and/or a constituent thereof.

Bakulesh et al teach compositions consisting of *Mycobacterium w* and/or constituents thereof (Abstract; Examples 1-7).

### **Conclusion**

9. Claims 23, 24, and 29 are rejected.
10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

May 3, 2010